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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,491	03/02/2000	Vivian Berlin	APBI-P06-036	4943

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/517,491

Applicant(s)

BERLIN, VIVIAN

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 51-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group XII in Supergroup C in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The amendment filed on 9-14-2001 is acknowledged. Claims 1-50 have been canceled. Claims 51-62 have been added. Claims 51-62 are pending and currently under examination to the extent they read on the elected invention (antibodies to mammalian PI3 {RAPT1-like} kinase with sequence of SEQ ID NO:12 or fragments thereof).

Information Disclosure Statement

The Information Disclosure Statement filed on 1-16-01 is acknowledged. An initialed copy is attached hereto. Please note that not all cited references were considered due to their unavailability. Said references will be considered when they become available.

Priority

The instant application is a continuation-in-part (CIP) of U.S. Application 08/250,795, filed on 5-27-1994. The instant claims are drawn to antibodies or fragments thereof that are immunoreactive with a mammalian RAPT1 protein comprising the sequence of SEQ ID NO:12. Said antibodies also do not substantially cross-react with a fungal TOR1 or TOR2 protein. However, since U.S. Application 08/250,795 does not disclose SEQ ID NO:12 or antibodies that

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are specifically immunoreactive to a RAPT1 protein and do not substantially cross react with a fungal TOR1 or TOR2 protein, the filing date of the instant application (3-2-2000) will be used with regard to the availability of prior art under 35 U.S.C. 102.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6-7, 9, 11, 13 and 16-17 of U.S. Patent No.

6,464,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to antibodies and antibody preparations that specifically immunoreact with proteins having greater than 90 percent identity with SEQ ID NO:12 and do not cross-react with proteins with less than 90 percent identity with SEQ ID NO:12 (i.e. fungal TOR1 and TOR2 proteins).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 53-54 are rendered vague and indefinite by the use of the term "immunoreactive". It is unclear what other "reaction" an antibody can have with a protein other than **binding**. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 51-55 57, 59 and 61 are rendered vague and indefinite by the use of the term "substantially cross-react". It is unclear degree of cross reactivity is represented by the term "substantially". As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-62 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berlin et al. (WO 95/33052).

The instant invention is drawn to antibody preparations (both monoclonal and polyclonal) that are specifically immunoreactive with a mammalian RAPT1 protein (or the fragment thereof represented by SEQ ID NO:12) and do not substantially cross react (binding affinity of less than 10 percent) with a fungal TOR1 or TOR2 protein.

Berlin et al. disclose the nucleic acid and amino acid sequence for mammalian RAPT1 (SEQ ID NO :11 and SEQ ID NO:12) which fully incorporates SEQ ID NO :12 of the instant application, as well as disclose the sequence of fragments of RAPT1 (see pages 67-104). Berlin et al. further disclose antibody preparations (both monoclonal and polyclonal) that are specifically immunoreactive with a mammalian RAPT1 protein and do not substantially cross react (binding affinity of less than 10 percent) with a fungal TOR1 or TOR2 protein (see page

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39, line 10 to page 40, line 27). Berlin et al. do not specifically disclose that the aforementioned antibodies are specifically immunoreactive with a RAPT1 protein having an amino acid sequence that is at least 90 percent identical to SEQ ID NO:12 of the instant application. However, since SEQ ID NO:12 codes for the biologically active region of the RAPT1 protein disclosed by Berlin et al., the antibodies raised against said RAPT1 protein would bind (i.e. immunoreact) with a protein with a 90 percent identity to SEQ ID NO:12. Hence, in the absence of evidence to the contrary, the antibody preparations of the instant application are merely obvious variants of the antibody preparations disclosed by Berlin et al. Berlin et al. does not explicitly disclose that the disclose recombinant antibodies with the aforementioned properties. However, sequencing a known antibody so that it can be produced recombinantly constitutes a standard laboratory practice and hence would have been obvious to one of ordinary skill in the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
January 9, 2003

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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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